Safety & Environmental Product Stewardship Initiatives

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Objective

To provide recommendations to align environmental, health and safety practices with new medical device/diagnostic product launches to yield:

- √ Customer benefits and
- √ Financial gains/cost savings.

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Imagine products with the following environmental impacts:

- Chemicals prohibited for your sites' or customers' waste discharge, such as mercury (thimerosol) used as a preservative above waste discharge limits, other heavy metals, phenols, formaldehyde.
- Ozone-depleting substances requiring special identification markings on products.
- Special DOT/IATA shipping requirements for reagents or biohazardous materials that are not properly identified.
- Materials that exceed production site's permitted levels. Such as a process discharge of a waste product that violates site's waste water restrictions for heavy metals.
- Packaging with large fees in certain countries due to non-recyclable components.
- Packaging with restricted delivery routes due to hazardous components.

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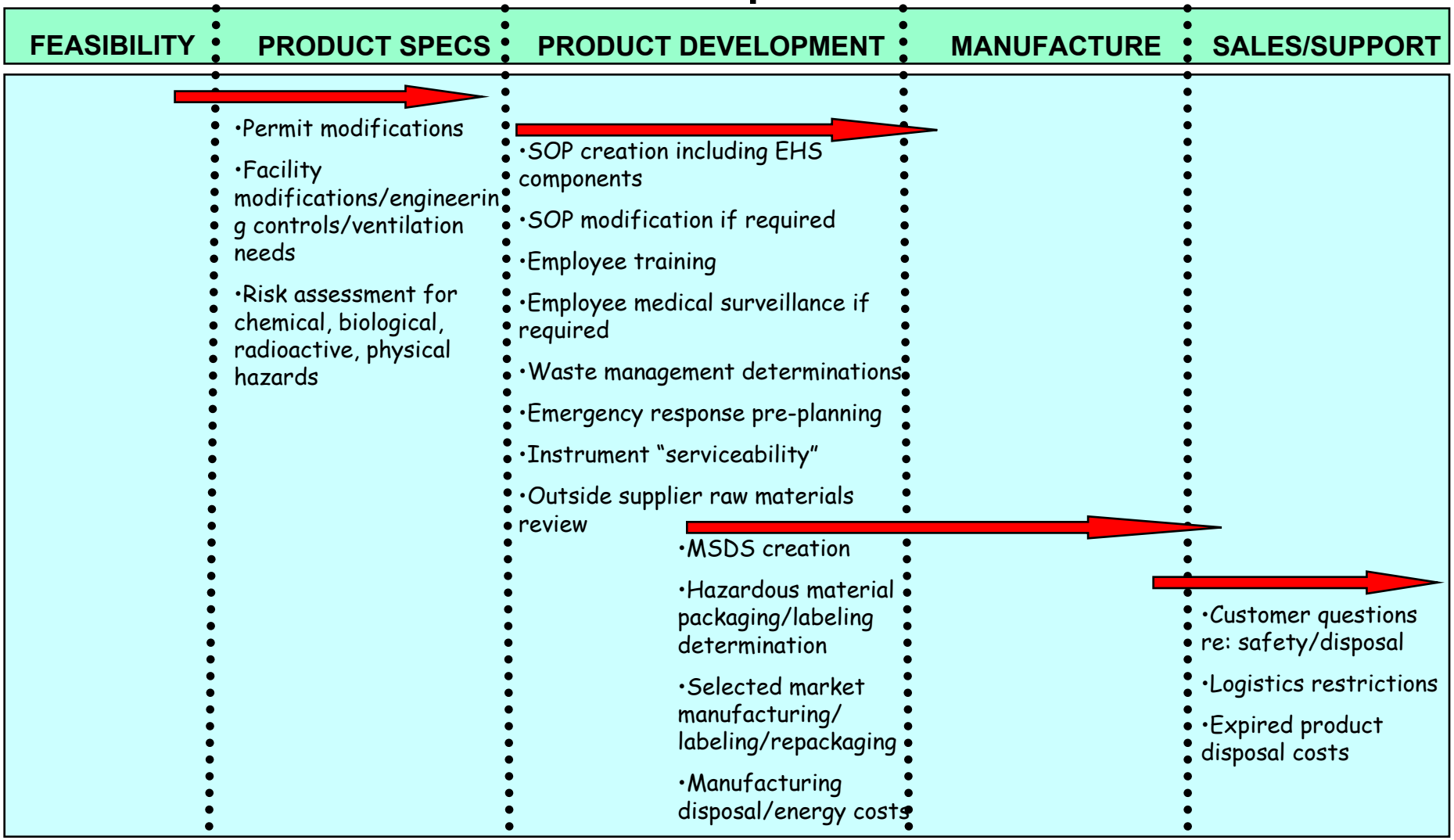
Imagine products with the following safety impacts:

- Regulated carcinogens requiring employee air sampling/medical surveillance that is not completed, i.e., reagents contain formaldehyde, methylene chloride.
- Reactive materials that must be specially stored, i.e., picric acid dries up and becomes shock-sensitive.
- Chemicals where gloves/engineering controls/training are not identified, i.e., chloroform used as cleaning agent without proper gloves and “hazard communication” training.
- Chemicals where spill response pre-planning is not addressed, i.e., highly toxic solvent requires special air monitoring devices to ensure clean-up.
- No MSDS upon reagent release for sale.
- Production steps that do not address ergonomic concerns, i.e., screw torquing requirements for sub-assembly result in carpal tunnel syndrome.

Typical EHS "Deliverables" & Product Development/Launch



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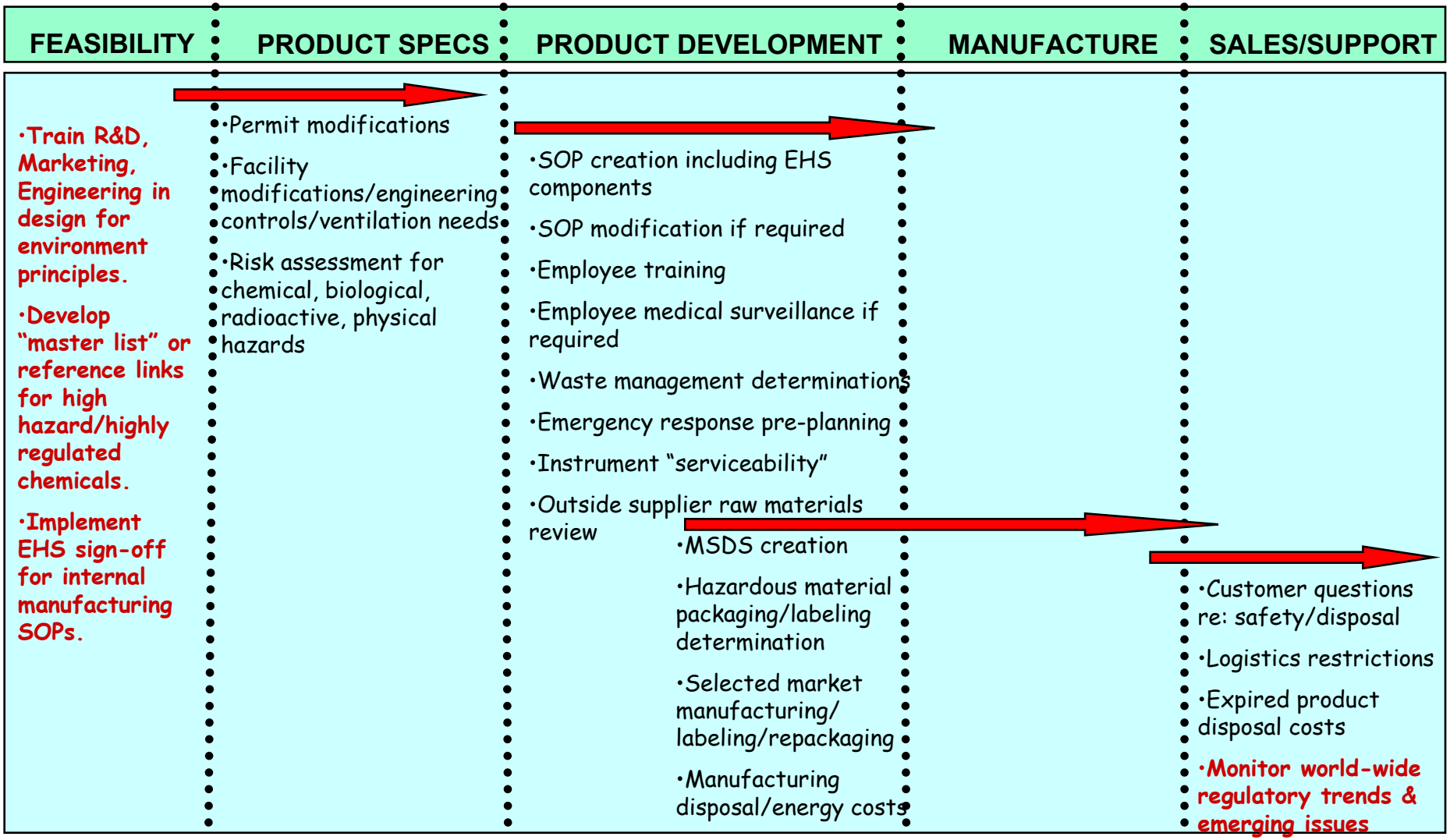
Typical EHS Proactive Actions & Product Development/Launch



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Challenges

- Avoiding perception that EHS is a potential bottleneck to product development timelines.
- Building relationships with key internal customers, especially project management, marketing and R&D.
- Complexity of worldwide regulatory market and emerging trends.
- Quantifying financial advantages.

Cost Benefits of Product Stewardship

- Improved safety and environmental regulatory compliance (programs are proactive vs. reactive).
- Adequate capital/expense planning for internal improvements needed to manufacture goods.
- Reduced packaging costs/duties.
- Improved time to market (all requirements are predicted and addressed).
- Increased marketability of goods (due to environmental or safety benefits to customer).
- Waste reduction for manufacturer and/or customer.